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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/843,051 | 04/26/2001 | Martin T. Gerber | P-8436.03CIP1 | 8909 |

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EXAMINER
EVANISKO, GEORGE ROBERT

ART UNIT 3762 PAPER NUMBER

DATE MAILED: 03/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/843,051 | GERBER ET AL. | |
| | Examiner | Art Unit | |
| | George R Evanisko | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 February 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 6, “further comprising...” is vague since the wire coil electrode should only be “comprising” the ring shaped electrode and wire coil” since there are not two wire coil electrodes; in line 7, “, an elongated” is vague since it should be “, and an elongated” since there are no other elements after the ring electrode and wire coil (it is unclear if there are other elements besides the ring and wire since the wire coil electrode uses “further comprises” and since there was no “and” to signal the last element); in line 8, “wire coil” is vague since it is unclear if this is in addition to the wire coil electrode; in line 9, “and electrically insulated from the lead conductor” is vague since the wire coil is connected to the ring electrode and the ring electrode is connected to the lead conductor and will inherently be electrically connected to the lead conductor (instead of electrically insulated); in line 9, “the electrode connector element coupled to the electrode connector” is vague since it is connected to itself.

In claims 8-10, “connector element” is vague since it is unclear if the first or second element is being discussed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al (5534022). Due to the numerous 112 second paragraph rejections, the examiner has interpreted the Hoffman reference as meeting the claimed limitations with reference to figures 7 and 13. In addition, Hoffman is capable of meeting the functional use recitations presented in the claims.

Claims 1, 2, 4, 7, 8, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Laske et al (5728149). Due to the numerous 112 second paragraph rejections, the examiner has interpreted the Laske reference as meeting the claimed limitations with reference to the figures. In addition, Hoffman is capable of meeting the functional use recitations presented in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman et al. Hoffman shows and describes how the wire coil is “coupled”, “butt-welded” or “adhered” to the connector element in connection with figure 7. In addition, it is noted that “adhered” means to hold fast as if by glue, fusing, etc, and Hoffman will meet this limitation.

Hoffman discloses the claimed invention except for the common inner diameters of the coil and connector element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Hoffman, with the common inner diameters of the coil and connector since it was known in the art that electrodes use common inner diameters for the coil and connector element to allow the lead conductor to easily pass by the wire coil electrode and provide a thin lead. In addition, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Hoffman with common inner diameters for the coil and connector element, because Applicant has not disclosed that the common inner diameters of the coil and connector element provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant’s invention to perform

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equally well with the inner diameters not being common as taught by Hoffman, because it provides an effective way to guide the lead conductor and/or allow the wire to easily be welded to the connector. Therefore, it would have been an obvious matter of design choice to modify Hoffman to obtain the invention as specified in the claim(s).

Claims 3, 9, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laske et al.

Laske discloses the claimed invention except for the butt weld of the coil to connector, the ring electrode proximal to the wire (claim 13) and a further ring electrode proximal to the wire coil electrode (claim14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Laske, with the butt weld of the coil to connector, the ring electrode proximal to the wire (claim 13) and a further ring electrode proximal to the wire coil electrode (claim14) since it was known in the art that leads use butt welds of the coil to connector to provide a quick, strong connection of the coil to the connector and since it was known in the art to have the ring electrode proximal to the wire (claim 13) and a further ring electrode proximal to the wire coil electrode (claim14) to provide other sensing or stimulating electrodes on the lead to further sense or stimulate other areas of the body.

Claims 5, 6, 11, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (or Laske).

Hoffman (or Laske) discloses the claimed invention except for the ring electrode having an opening through the side wall that the distal end of the conductor is extended through and attached to the side wall and the length of the electrode being from 10 mm to about 38 mm with

an outer diameter in the range of 0.5 mm to 2.0 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Hoffman (or Laske), with the ring electrode having an opening through the side wall that the distal end of the conductor is extended through and attached to the side wall and the length of the electrode being from 10 mm to about 38 mm with an outer diameter in the range of 0.5 mm to 2.0 mm since it was known in the art that leads are provided with ring electrodes having an opening through the side wall that the distal end of the conductor is extended through and attached to the side wall to provide a lead conductor connection that is more resistant to breakage and since it was known in the art to provide leads with the length of the electrode being from 10 mm to about 38 mm with an outer diameter in the range of 0.5 mm to 2.0 mm to provide an electrode that decreases the current density of the stimulus and/or to allow the electrode to be easily placed next to a stimulation area and to provide a lead that is small and less obtrusive.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703 306-4520 for regular communications and 703 306-4520 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko
Primary Examiner
Art Unit 3762

7/19/3

GRE
March 18, 2003